

Calendar No. 457

110TH CONGRESS  
1ST SESSION**H. R. 2295**

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IN THE SENATE OF THE UNITED STATES

OCTOBER 17, 2007

Received

OCTOBER 30, 2007

Read the first time

OCTOBER 31, 2007

Read the second time and placed on the calendar

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**AN ACT**

To amend the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis Registry.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “ALS Registry Act”.

5 **SEC. 2. FINDINGS.**

6 Congress makes the following findings:

1           (1) Amyotrophic lateral sclerosis (referred to in  
2       this section as “ALS”) is a fatal, progressive  
3       neurodegenerative disease that affects motor nerve  
4       cells in the brain and the spinal cord.

5           (2) The average life expectancy for a person  
6       with ALS is 2 to 5 years from the time of diagnosis.

7           (3) The cause of ALS is not well understood.

8           (4) There is only one drug currently approved  
9       by the Food and Drug Administration for the treat-  
10      ment of ALS, which has thus far shown only modest  
11      effects, prolonging life by just a few months.

12          (5) There is no known cure for ALS.

13          (6) More than 5,000 individuals in the United  
14      States are diagnosed with ALS annually and as  
15      many as 30,000 individuals may be living with ALS  
16      in the United States today.

17          (7) Studies have found relationships between  
18      ALS and environmental and genetic factors, but  
19      those relationships are not well understood.

20          (8) Scientists believe that there are significant  
21      ties between ALS and other motor neuron diseases.

22          (9) Several ALS disease registries and data-  
23      bases exist in the United States and throughout the  
24      world, including the SOD1 database, the National  
25      Institute of Neurological Disorders and Stroke re-

1        pository, and the Department of Veterans Affairs  
2        ALS Registry.

3            (10) A single national system to collect and  
4        store information on the prevalence and incidence of  
5        ALS in the United States does not exist.

6            (11) In each of fiscal years 2006 and 2007,  
7        Congress directed \$887,000 to the Centers for Dis-  
8        ease Control and Prevention to begin a nationwide  
9        ALS registry.

10          (12) The Centers for Disease Control and Pre-  
11        vention and the Agency for Toxic Substances and  
12        Disease Registry have established three pilot  
13        projects, beginning in fiscal year 2006, to evaluate  
14        the science to guide the creation of a national ALS  
15        registry.

16          (13) The establishment of a national registry  
17        will help—

18            (A) to identify the incidence and preva-  
19        lence of ALS in the United States;

20            (B) to collect data important to the study  
21        of ALS;

22            (C) to promote a better understanding of  
23        ALS;

1 (D) to collect information that is impor-  
2 tant for research into the genetic and environ-  
3 mental factors that cause ALS;

4 (E) to strengthen the ability of a clearing-  
5 house—

6 (i) to collect and disseminate research  
7 findings on environmental, genetic, and  
8 other causes of ALS and other motor neu-  
9 ron disorders that can be confused with  
10 ALS, misdiagnosed as ALS, and in some  
11 cases progress to ALS;

12 (ii) to make available information to  
13 patients about research studies for which  
14 they may be eligible; and

15 (iii) to maintain information about  
16 clinical specialists and clinical trials on  
17 therapies; and

18 (F) to enhance efforts to find treatments  
19 and a cure for ALS.

20 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**  
21 **ACT.**

22 Part P of title III of the Public Health Service Act  
23 (42 U.S.C. 280g et seq.) is amended by adding at the end  
24 the following:

1 **“SEC. 399R. AMYOTROPHIC LATERAL SCLEROSIS REG-**  
2 **ISTRY.**

3 “(a) ESTABLISHMENT.—

4 “(1) IN GENERAL.—Not later than 1 year after  
5 the receipt of the report described in subsection  
6 (b)(3), the Secretary, acting through the Director of  
7 the Centers for Disease Control and Prevention and  
8 in consultation with a national voluntary health or-  
9 ganization with experience serving the population of  
10 individuals with amyotrophic lateral sclerosis (re-  
11 ferred to in this section as ‘ALS’), shall—

12 “(A) develop a system to collect data on  
13 ALS and other motor neuron disorders that can  
14 be confused with ALS, misdiagnosed as ALS,  
15 and in some cases progress to ALS, including  
16 information with respect to the incidence and  
17 prevalence of the disease in the United States;  
18 and

19 “(B) establish a national registry for the  
20 collection and storage of such data to include a  
21 population-based registry of cases in the United  
22 States of ALS and other motor neuron dis-  
23 orders that can be confused with ALS,  
24 misdiagnosed as ALS, and in some cases  
25 progress to ALS.

1           “(2) PURPOSE.—It is the purpose of the reg-  
2           istry established under paragraph (1)(B) to gather  
3           available data concerning—

4                   “(A) ALS, including the incidence and  
5                   prevalence of ALS in the United States;

6                   “(B) the environmental and occupational  
7                   factors that may be associated with the disease;

8                   “(C) the age, race or ethnicity, gender, and  
9                   family history of individuals who are diagnosed  
10                  with the disease;

11                  “(D) other motor neuron disorders that  
12                  can be confused with ALS, misdiagnosed as  
13                  ALS, and in some cases progress to ALS; and

14                  “(E) other matters as recommended by the  
15                  Advisory Committee established under sub-  
16                  section (b).

17           “(b) ADVISORY COMMITTEE.—

18                   “(1) ESTABLISHMENT.—Not later than 90 days  
19                   after the date of the enactment of this section, the  
20                   Secretary, acting through the Director of the Cen-  
21                   ters for Disease Control and Prevention, shall estab-  
22                   lish a committee to be known as the Advisory Com-  
23                   mittee on the National ALS Registry (referred to in  
24                   this section as the ‘Advisory Committee’). The Advi-  
25                   sory Committee shall be composed of at least one

1 member, to be appointed by the Secretary, acting  
2 through the Director of the Centers for Disease  
3 Control and Prevention, representing each of the fol-  
4 lowing:

5 “(A) National voluntary health associa-  
6 tions that focus solely on ALS and have dem-  
7 onstrated experience in ALS research, care, and  
8 patient services, as well as other voluntary asso-  
9 ciations focusing on neurodegenerative diseases  
10 that represent and advocate on behalf of pa-  
11 tients with ALS and patients with other motor  
12 neuron disorders that can be confused with  
13 ALS, misdiagnosed as ALS, and in some cases  
14 progress to ALS.

15 “(B) The National Institutes of Health, to  
16 include, upon the recommendation of the Direc-  
17 tor of the National Institutes of Health, rep-  
18 resentatives from the National Institute of Neu-  
19 rological Disorders and Stroke and the National  
20 Institute of Environmental Health Sciences.

21 “(C) The Department of Veterans Affairs.

22 “(D) The Agency for Toxic Substances  
23 and Disease Registry.

24 “(E) The Centers for Disease Control and  
25 Prevention.

1           “(F) Patients with ALS or their family  
2 members.

3           “(G) Clinicians with expertise on ALS and  
4 related diseases.

5           “(H) Epidemiologists with experience in  
6 data registries.

7           “(I) Geneticists or experts in genetics who  
8 have experience with the genetics of ALS or  
9 other neurological diseases.

10          “(J) Statisticians.

11          “(K) Ethicists.

12          “(L) Attorneys.

13          “(M) Other individuals with an interest in  
14 developing and maintaining the National ALS  
15 Registry.

16          “(2) DUTIES.—The Advisory Committee shall  
17 review information and make recommendations to  
18 the Secretary concerning—

19               “(A) the development and maintenance of  
20 the National ALS Registry;

21               “(B) the type of information to be col-  
22 lected and stored in the Registry;

23               “(C) the manner in which such data is to  
24 be collected;



1           “(D) the use and availability of such data  
2           including guidelines for such use; and

3           “(E) the collection of information about  
4           diseases and disorders that primarily affect  
5           motor neurons that are considered essential to  
6           furthering the study and cure of ALS.

7           “(3) REPORT.—Not later than 1 year after the  
8           date on which the Advisory Committee is estab-  
9           lished, the Advisory Committee shall submit a report  
10          concerning the review conducted under paragraph  
11          (2) that contains the recommendations of the Advi-  
12          sory Committee with respect to the results of such  
13          review.

14          “(c) GRANTS.—Notwithstanding the recommenda-  
15          tions of the Advisory Committee under subsection (b), the  
16          Secretary, acting through the Director of the Centers for  
17          Disease Control and Prevention, may award grants to, and  
18          enter into contracts and cooperative agreements with, pub-  
19          lic or private nonprofit entities for the collection, analysis,  
20          and reporting of data on ALS and other motor neuron  
21          disorders that can be confused with ALS, misdiagnosed  
22          as ALS, and in some cases progress to ALS.

23          “(d) COORDINATION WITH STATE, LOCAL, AND FED-  
24          ERAL REGISTRIES.—

1           “(1) IN GENERAL.—In establishing the Na-  
2           tional ALS Registry under subsection (a), the Sec-  
3           retary, acting through the Director of the Centers  
4           for Disease Control and Prevention, shall—

5                   “(A) identify, build upon, expand, and co-  
6                   ordinate among existing data and surveillance  
7                   systems, surveys, registries, and other Federal  
8                   public health and environmental infrastructure  
9                   wherever possible, including—

10                           “(i) the 3 ALS registry pilot projects  
11                           initiated in fiscal year 2006 by the Centers  
12                           for Disease Control and Prevention and  
13                           the Agency for Toxic Substances and Dis-  
14                           ease Registry at the South Carolina Office  
15                           of Research & Statistics; the Mayo Clinic  
16                           in Rochester, Minnesota; and Emory Uni-  
17                           versity in Atlanta, Georgia;

18                           “(ii) the Department of Veterans Af-  
19                           fairs ALS Registry;

20                           “(iii) the DNA and Cell Line Reposi-  
21                           tory of the National Institute of Neuro-  
22                           logical Disorders and Stroke Human Ge-  
23                           netics Resource Center;

24                           “(iv) the Agency for Toxic Substances  
25                           and Disease Registry studies, including

1 studies conducted in Illinois, Missouri, El  
2 Paso and San Antonio, Texas, and Massa-  
3 chusetts;

4 “(v) State-based ALS registries, in-  
5 cluding the Massachusetts ALS Registry;

6 “(vi) the National Vital Statistics Sys-  
7 tem; and

8 “(vii) any other existing or relevant  
9 databases that collect or maintain informa-  
10 tion on those motor neuron diseases rec-  
11 ommended by the Advisory Committee es-  
12 tablished in subsection (b); and

13 “(B) provide for research access to ALS  
14 data as recommended by the Advisory Com-  
15 mittee established in subsection (b) to the ex-  
16 tent permitted by applicable statutes and regu-  
17 lations and in a manner that protects personal  
18 privacy consistent with applicable privacy stat-  
19 utes and regulations.

20 “(2) COORDINATION WITH NIH AND DEPART-  
21 MENT OF VETERANS AFFAIRS.—Notwithstanding the  
22 recommendations of the Advisory Committee estab-  
23 lished in subsection (b), and consistent with applica-  
24 ble privacy statutes and regulations, the Secretary  
25 shall ensure that epidemiological and other types of

1 information obtained under subsection (a) is made  
2 available to the National Institutes of Health and  
3 the Department of Veterans Affairs.

4 “(e) DEFINITION.—For the purposes of this section,  
5 the term ‘national voluntary health association’ means a  
6 national non-profit organization with chapters or other af-  
7 filiated organizations in States throughout the United  
8 States.

9 “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
10 are authorized to be appropriated to carry out this section,  
11 \$25,000,000 for fiscal year 2008, and \$16,000,000 for  
12 each of the fiscal years 2009 through 2012.”.

Passed the House of Representatives October 16,  
2007.

Attest: LORRAINE C. MILLER,  
*Clerk.*



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110<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

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